K053279

DEC 2 2 2005

510(k) SUMMARY

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Applicant

PCK Electronic Industry and Trade Company, LTD, Inc.
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Phone: (312) 267-2046
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Contact Person: Cengiz Kabakci, General Manager

2. Device Identification

Proprieatary Device Name:	UroVantage
Common/Generic Device Name:	Urological Table
Classification Name:	Image-Intensified Fluoroscopic X-Ray System, Radiological Table
Product Code:	JAA, IXR
Regulatory Class:	Class II, Class II 510(k) Exempt
Regulation Number:	21 CFR § 892.1650, 21 CFR § 892.1980

3. Substantial Equivalence

The UroVantage Urological Table is substantially equivalent to the following currently marketed device:

- UROlogic, (K011311), PCK Electronic Industry and Trade Company, LTD

4. Description of Device

The UroVantage is an Image-Intensified Fluoroscopic X-Ray System and radiological table. The device consists of: a tilting patient support table; x-ray generator; mobile control panel; remote control panel, x-ray tube assembly, collimator, image intensifier, television ("TV") system with monitor; tableside control unit; and foot control. The Isocentric C-arm of the UroVantage ensures easy movement of the image intensifier and x-ray tube around the patient. The device's floor mounted x-ray stand with a tilting table also provides support for both the table and the Isocentric C-arm. Standard and optional accessories also are supplied.

The UroVantage is a modification to PCK's UROlogic device that has already been cleared by FDA to provide fluoroscopic and radiographic imaging of the patient

during diagnostic, surgical and interventional procedures (K011311). The UroVantage has the same intended use and fundamental scientific technology as the UROlogic. The primary modifications are: (1) replacement of the fixed imaging arm ("U" arm) with an Isocentric C-Arm; (2) the fixation of the Isocentric C-arm to the support table; (3) minor changes in the dimensions of the support table; and (4) changes in the software to accommodate the use of the Isocentric C-arm.

5. Intended Use

The UroVantage is intended to provide fluoroscopic and radiographic imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include but are not limited to urologic and endoscopic procedures. The system may be used for other imaging applications at physician's discretion

6. Technological Characteristics

UroVantage Urological Table employs the same technological characteristics as the UROlogic. The UroVantage has the same intended use and indications for use as the UROlogic. Both systems are image intensified x-ray imaging systems with an overtable x-ray tube assembly. Like the UROlogic, the UroVantage consists of a patient suport table, and standard system components: x-ray generator, x-ray tube, Image Intensifier, TV system and monitor(s).

7. Conclusion

The UroVantage has the same intended use and indications for use as the predicate UROlogic. The UroVantage also has very similar technological characteristics, and principles of operation as its predicate. Although there are minor differences between the UroVantage and UROlogic, those differences do not raise any new questions of safety or efficacy. Thus, the UroVantage is substantially equivalent to the UROlogic product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

AUG 23 2013

PCK Electronic Industry and Trade Co., Ltd
% Mr. Jonathan S. Kahn, Esq.
Hogan & Hartson, L.L.P.
555 13th Street, NW
WASHINGTON DC 20004

Re: K053279
Trade/Device Name: UROVantage (Urology x-ray table)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: November 23, 2005
Received: November 30, 2005

Dear Mr. Kahn:

This letter corrects our substantially equivalent letter of December 22, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

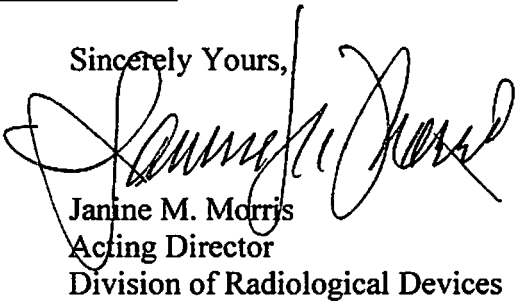
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):_____

Device Name: UROVANTAGE

Indications for Use: The UroVantage is intended to provide fluoroscopic and radiographic imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include but are not limited to Urologic and endoscopic procedures. The system may be used for other imaging applications at physician's discretion

Prescription Use __YES✓ AND/OR Over-The-Counter Use_NO
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Feygin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053279